



Health Research Authority

North West – Preston Research Ethics Committee

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Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

16 March 2017

Professor Claire Foster
Professor of Psychosocial Oncology & Director of Macmillan Survivorship Research Group
University of Southampton
Faculty of Health Sciences, Building 67
Highfield Campus, University of Southampton
University Road, Southampton
SO17 1BJ

Dear Professor Foster

Study title: HORIZONS: a cohort study to explore recovery of health and well-being in adults diagnosed with cancer
REC reference: 16/NW/0425
Protocol number: RHM CAN1199
Amendment number: 4
Amendment date: 27 February 2017
IRAS project ID: 202342

Updated questionnaires, 9 month timepoint questionnaire, flyer for on line follow up, updated email, addition of 4 sites (Barts Health NHS Trust, St George's University Hospitals NHS Foundation Trust, NHS Lanarkshire, NHS Highlands)

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The members had no ethical issues with this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Flyer]	1	27 February 2017
Covering letter on headed paper		10 March 2017
Non-validated questionnaire [contents 3 month]		
Non-validated questionnaire [contents 9 month]		
Non-validated questionnaire [contents baseline]		
Non-validated questionnaire [3 month BREAST]	2	27 February 2017
Non-validated questionnaire [3 month CERVICAL]	2	27 February 2017
Non-validated questionnaire [3 month ENDOMETRIAL]	2	27 February 2017
Non-validated questionnaire [3 month NHL]	2	27 February 2017
Non-validated questionnaire [3 month OVARIAN]	2	27 February 2017
Non-validated questionnaire [9 month BREAST]	1	27 February 2017
Non-validated questionnaire [9 month CERVICAL]	1	27 February 2017
Non-validated questionnaire [9 month ENDOMETRIAL]	1	27 February 2017
Non-validated questionnaire [9 month NHL]	1	27 February 2017
Non-validated questionnaire [9 month OVARIAN]	1	27 February 2017
Non-validated questionnaire [baseline CERVICAL]	1	27 February 2017
Non-validated questionnaire [baseline ENDOMETRIAL]	1	27 February 2017
Non-validated questionnaire [baseline OVARIAN]	1	27 February 2017
Non-validated questionnaire [baseline BREAST]	2	27 February 2017
Non-validated questionnaire [baseline NHL]	2	27 February 2017
Notice of Substantial Amendment (non-CTIMP)	4	27 February 2017
Other [on line questionnaire email text]	1	01 March 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

16/NW/0425: Please quote this number on all correspondence

Yours sincerely




Dr Rob Monks
Chair

E-mail: nrescommittee.northwest-lancaster@nhs.net

Enclosures: List of names and professions of members who took part in the review

*Copy to: Mrs Sharon Davies-Dear, University Hospital Southampton NHS Foundation Trust
Miss Becci Petch*

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Attendance at Sub-Committee of the REC meeting March 2017

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Carol Haigh		Yes	
Dr Rob Monks	Senior Lecturer	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Carol Ebenezer	REC Manager